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(54) Title: HYDROGEL WOUND DRESSING AND THE METHOD OF MAKING AND USING THE SAME (57) Abstract A hydrogel wound dressing which is highly absorptive, contours to a wound side and maintains the wound in a moist state to promote healing thereof.		

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HYDROGEL WOUND DRESSING AND THE METHOD
OF MAKING AND USING THE SAME

Field of the Invention

The present invention relates to a hydrogel wound
5 dressing and a method of making and using the same. More
particularly, the present invention relates to a flexible
hydrogel wound dressing which is highly absorptive, contours
to a wound site and maintains a wound in a moist state to
promote healing thereof and the method of producing and
10 using the same.

Background of the Invention

The treatment of draining wounds is a problem in the
medical profession. Wound exudate such as blood, serum and
purulent matter from a draining wound can lead to bacterial
15 growth and delayed healing if not treated properly. Often
times it is difficult to maintain wounds free of such wound
secretions to allow for healing. Another concern in treating
such draining wounds is that some believe that allowing a
wound to heal in a slightly moist state may actually
20 accelerate healing. Accordingly, the medical profession
desires a means for maintaining draining wounds in a clean,
moist protected state.

Currently in an attempt to meet such wound treatment
needs there are wound exudate absorption compositions which
25 are comprised of hydrogel materials in powder form. One
example of such a powder material includes dextranomer
beads. Dextranomer beads are hydrophilic spherical beads
which are applied to a wound to absorb wound exudate.
Disadvantages noted in using materials in powder form
30 include difficulty in achieving even application, difficulty
with lumping and clumping of the material after application

and difficulty in removing the material from a wound site without damaging newly formed tissues in the wound.

U.S. Patent No. 4,226,232 discloses the blending of a hydrogel material with a liquid curing agent such as polyethylene glycol prior to introducing the material to a wound. A difficulty observed in the use of this material is that it can not be sterilized by irradiation due to the formation of free radicals within the gel material. These free radicals so formed within the gel material cause an instability of the hydrogel product thereby shortening the shelf life thereof.

U.S. Patent No. 5,059,424 discloses a wound dressing comprising a backing member with an adhesive layer and a hydrogel material layer of 15-30% polyhydric alcohol, 8-14% iso phorone diisocyanate prepolymer, 5-10% polyethylene oxide-based diamine, 0-1% salt and the balance water. Difficulties associated with the use of this wound product includes the limitation of not being able to cut the dressing to a size appropriate for the particular wound site and still have the backer intact. Additionally, the hydrogel material disclosed in this patent lacks the necessary strength to be used and removed in tact without the added support of the backer material.

The need exists for a sterile wound dressing which provides a size appropriate protective covering for a draining wound capable of absorbing exudate from the wound. It is also desirable to have a wound dressing suitable to protect a wound from debris and foreign matter capable of contaminating the wound. It is also desirable to have a wound dressing which cushions a wound from pressure. It is also desirable to have a wound dressing which does not adhere to new tissue forming in a wound. It is also

desirable to have a wound dressing which maintains a wound in a slightly moist state to promote healing.

Summary of the Invention

The present invention relates to a transparent,
5 insoluble hydrogel wound dressing capable of absorbing exudate from a draining wound without becoming adhered thereto. The subject wound dressing maintains a wound in a slightly moist state to promote healing of the wound while retaining its overall strength to allow for removal thereof
10 in a unitary fashion.

The hydrogel wound dressing of the present invention is a polyurethane hydrogel material comprising polyurethane prepolymer, deionized water, glycols, polyalkyldiamine and optionally an antimicrobial and/or a bacteriostatic agent.

15 The method of producing the hydrogel material of the present invention involves hydrolysis and addition reactions to produce a three-dimensional cross-linked polyurethane hydrogel as described in more detail below. The resultant polyurethane hydrogel material is blended and cast molded to
20 allow for complete gelatinization thereof in less than 180 minutes at room temperature. Gelatinization preferably begins within 30 to 40 minutes. The subject bubble-free hydrogel wound dressing is then optionally subjected to temperatures below 0° C to remove excess water prior to
25 packaging and sterilization using radiation sterilization or other suitable sterilization technique known to those skilled in the art prior to distribution.

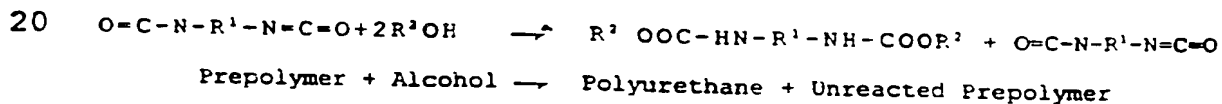
Detailed Description of the Invention

The polyurethane hydrogel wound dressing of the present
30 invention is capable of absorbing moisture from a wound site until the overall composition comprises approximately 70

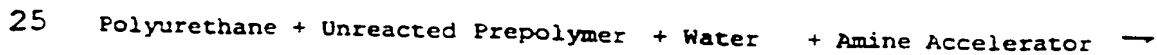
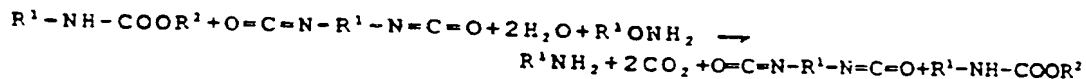
percent to 99 percent water or fluid. The subject non-adhesive hydrogel dressing provides for moist wound healing, absorbs wound exudate, allows for relatively fewer dressing changes, allows for easy removal with no trauma to a wound, protects a wound from contamination and minimizes wound odor.

The polyurethane hydrogel material of the present invention is generally produced by the formation of carbamate (urethane) linkages by the reaction of isocyanates with alcohols and by the formation of urea linkages through the reaction of isocyanates with water. These reactions are achieved by blending a polyoxyethylene-rich isophorone diisocyanate terminated oligomer, i.e., a polyurethane prepolymer, with a polyetherdiamine chain modifier having a predominately polyethylene oxide backbone and an approximate molecular weight between 500 and 5,000, deionized water, propylene glycol and polyethylene glycol in accordance with the following reactions:

STEP 1:



STEP 2:



Polyamine (unstable intermediate) + Carbon Dioxide + Unreacted Prepolymer + Polyurethane

STEP 3:



Polyurethane + Unreacted Prepolymer \rightarrow Polyurea (stable) + Polyurethane + Polyamine (unstable intermediate)

wherein the R¹ groups may be the same or different selected from the group consisting of C₁₋₁₂ alkyl repeating groups such as for example methyl, ethyl or propyl but preferably propyl for increased strength and stability; C₁₋₁₂ mono-or poly-hydroxyalkyl repeating groups such as for example hydroxymethyl or dihydroxypropyl but preferably dihydroxypropyl for increased strength and stability; C₁₋₁₂ acyl repeating groups such as for example acetyl or proprionyl but preferably proprionyl for increased strength and stability; C₁₋₁₂ alkoxyalkyl repeating groups such as for example methoxyethyl or ethoxypropyl but preferably ethoxypropyl for increased strength and stability; C₁₋₁₂ aminoalkyl repeating groups such as for example aminomethyl or aminopropyl but preferably aminopropyl for increased strength and stability; C₁₋₁₂ acylaminoalkyl repeating groups such as for example acetylaminomethyl or proprionylaminomethyl but preferably proprionylaminomethyl for increased strength and stability; C₁₋₁₂ oxyalkyl repeating groups such as but not limited to oxyethylene, oxypropylene or oxybutylene but preferably oxyethylene and/or oxypropylene to increase clarity, such repeating units having an average molecular weight of about 7,000 to about 30,000 capped with aromatic, aliphatic or cycloaliphatic isocyanates, diisocyanates or polyisocyanates, but most preferably diisocyanate- or polyisocyanate-capped repeating units as described above having molecular weights of at least 10,000. The use of aliphatic polyisocyanates is preferred in the present invention to achieve a greater degree of handling freedom since aliphatic isocyanate-capped prepolymers typically require longer periods of time for gelatinization. In

addition, aliphatic polyisocyanates will be preferred when the material is intended to be used in medical applications, because of increased biocompatibility and decreased toxicological considerations. By contrast, prepolymers capped with aromatic polyisocyanates gelatinize in about 30 to 60 seconds as opposed to 20 to 90 minutes as typical for aliphatic isocyanates. Gelatinization within 30 to 60 seconds is a disadvantage for use in the present application due to a lack of adequate time for proper blending of the materials and molding thereof. The subject reaction mixture forms a hydrogel in approximately 15 to 180 minutes at room temperature but preferably in approximately 15 to 90 minutes. Gelatinization can also be accelerated if desired with the use of a standard curing oven. A preferred method of accelerating gelatinization has been found to include heating the composition at approximately 30 to 80 degrees Celsius for 5 to 40 minutes but more preferably at approximately 45 degrees Celsius for 30 minutes.

Examples of suitable difunctional and polyfunctional isocyanates include but are not limited to isophorone diisocyanate, toluene-2,4-diisocyanate, toluene-2,6-diisocyanate, mixtures of toluene-2,4, and 2,6-diisocyanate, ethylene diisocyanate, ethylidene diisocyanate, propylene-1,2-diisocyanate, cyclohexylene-1,2-diisocyanate, cyclohexylene-1,4-diisocyanate, m-phenylene diisocyanate, 3,3'-diphenyl-4,4'-biphenylene diisocyanate, 4,4'-biphenylene diisocyanate, 4,4'-diphenylmethane diisocyanate, 3,3'-dichloro-4,4'-biphenylene diisocyanate, 1,6-hexamethylene diisocyanate, 1,4-tetramethylene diisocyanate, 1,10-decamethylene diisocyanate, cumene-2,4-diisocyanate, 1,5-naphthalene diisocyanate, methylene dicyclohexyl diisocyanate, 1,4-cyclohexylene diisocyanate, p-tetramethylxylylene diisocyanate, p-phenylene diisocyanate, 4-methoxy-

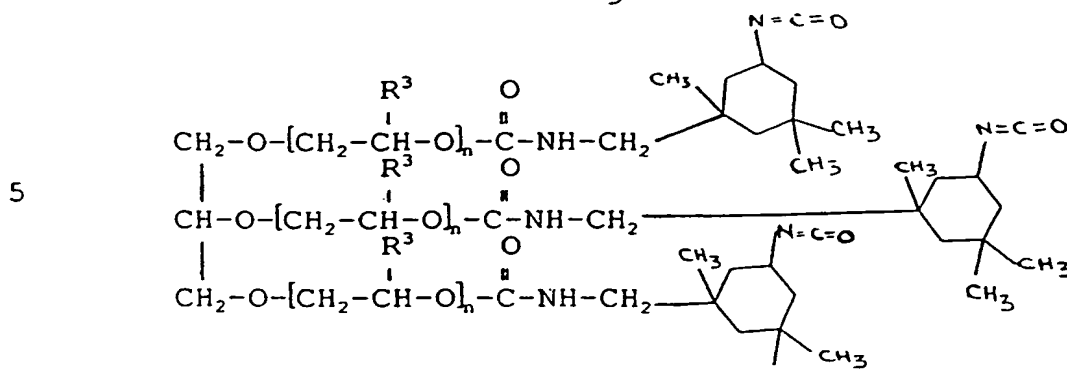
1,3-phenylene diisocyanate, 4-chloro-1,3-phenylene diisocyanate, 4-bromo-1,3-phenylene diisocyanate, 4-ethoxy-1,3-phenylene diisocyanate, 2,4-dimethylene-1,3-phenylene diisocyanate, 5,6-dimethyl-1,3-phenylene diisocyanate, 2,4-diisocyanatodiphenylether, 4,4'-diisocyanatodiphenylether, benzidine diisocyanate, 4,6-dimethyl-1,3-phenylene diisocyanate, 9,10-anthracene diisocyanate, 4,4'-diisocyanatodibenzyl, 3,3'-dimethyl-4,4'-diisocyanatodiphenylmethane, 2,6-dimethyl-4,4'-diisocyanatodiphenyl, 2,4-diisocyanatostilbene, 3,3'-dimethoxy-4,4'-diisocyanatodiphenyl, 1,4-anthracenediisocyanate, 2,5-fluorenediisocyanate, 1,8-naphthalene diisocyanate, 2,6-diisocyanatobenzfuran, 2,4,6-toluene triisocyanate, p,p',p"-triphenylmethane triisocyanate, trifunctional trimer of isophorone diisocyanate, trifunctional biuret of hexamethylenediisocyanate, trifunctional trimer of hexamethylene diisocyanate and polymeric 4,4'-diphenylmethane diisocyanate, but preferably diisophorone diisocyanate or isophorone diisocyanate for a preferred rate of gelatinization.

R^2OH is selected from the group consisting of C_{1-12} monohydric alcohols such as ethanol, methanol or propanol, but preferably ethanol for improved biocompatibility, C_{1-12} diols such as alkyl glycols and derivatives thereof wherein propylene glycol is preferred for improved biocompatibility, and C_{1-12} polyalkyldiols such as polypropylene glycol, polyethylene glycol or polybutylene glycol wherein polyethylene glycol is preferred for better biocompatibility. Most preferably, propylene glycol and/or polyethylene glycol is used in the present invention for biocompatibility. Additionally, R^2 represents the corresponding C_{1-12} alkyl group, such as methyl, ethyl or

propyl but most preferably methyl for improved stability, C₁₋₁₂ hydroxyalkyl group such as hydroxy methyl hydroxyethyl or hydroxypropyl but most preferably hydroxy methyl for improved stability, or C₁₋₁₂ polyhydroxyalkyl group derived from R²OH such as polyhydroxymethyl, polyhydroxyethyl, and polyhydroxypropyl but preferably polyhydroxymethyl for improved stability. The resultant clear or transparent product of the subject invention allows for undisturbed viewing of a wound for better wound care management.

The above noted chemical reactions illustrate the process by which the subject hydrogel is produced. In the initial step, as illustrated in STEP 1, an alcohol is reacted with a polyurethane prepolymer such as a isophorone diisocyanate prepolymer but preferably a prepolymer of the following chemical composition

9



10 wherein the R^3 groups may be the same or different selected from the group consisting of hydrogen and C_{1-10} alkyl group such as for example methyl or ethyl but preferably methyl for improved stability; and n represents integers which may differ from one another within the range of 1 to 200. A

15 mixture of hydrogen and methyl groups are the preferred R^3 groups for the above-described prepolymer in order to increase the flexibility and hydrophilicity of the final hydrogel product. The prepolymer is reacted with a C_{1-12} alcohol, C_{1-12} diol, C_{1-12} alkyldiol and/or C_{1-12} polyalkyldiol

20 as described above, such as polyethylene glycol or propylene glycol in an alcoholysis reaction to form a polyurethane. Next, as illustrated in STEP 2 unreacted prepolymer further reacts with water and the polyalkoxyamine accelerator to undergo a hydrolysis reaction to form a polyamine and carbon

25 dioxide. Due to the fact that the polyamine produced in STEP 2 is an unstable intermediate in this reaction process, STEP 3 illustrates the continued reaction of the polyamine of STEP 2, undergoing an addition reaction to form a stable polyurea. The rate of gelatinization for the polyurea is

30 increased through the addition of the accelerator. Suitable accelerators include sodium carbonate, carbonate salts, sodium hydroxide, sodium citrate, potassium phosphate, ammonia, and polyalkoxyamines such as but not limited to polyetheramine due to its solubility and gelatinization

35 acceleration capability. It has been found that such

accelerators which are water soluble and have a molecular weight of preferably 200 to 5,000 improve polymerization rates. The series of reactions just described rather than producing a foam, results in a three-dimensional cross-linked polyurethane/polyurea hydrogel. It is important to note that the water is added at the end of the second step of the procedure in order to prevent premature gelatinization and foaming. Additionally, the percentage of free isocyanate present in the prepolymer directly affects the gelatinization reaction rate. For this reason, in the present invention the percentage of free isocyanate present in the reaction mixture is strictly controlled to a level below 5 percent to slow the reaction and slow gelatinization. Another consideration to be noted is that the faster the reaction rate, the faster the carbon dioxide gas is produced, which if not properly controlled causes the formation of a foam rather than a hydrogel. It is the control of these critical factors, i.e., the percentage of isocyanate present, the reaction rate and the gelatinization rate among the other considerations noted herein, which allows one to produce the unexpectedly superior hydrogel of the present invention.

In order for one to achieve the desired reaction mixture of the present invention and form a hydrogel of desirable strength and integrity for the intended use, STEP 1 involves blending together approximately 25 to 70 percent of the polyurethane prepolymer but preferably approximately 60.5 percent and approximately 30 to 75 percent of a polyalkyl diol such as polyethylene glycol but preferably approximately 39.5 percent to produce Product A. STEP 2 involves combining approximately 50 to 90 percent deionized water but most preferably approximately 74.2 percent, approximately .2 to 10 percent of a polyalkoxyamine such as

polyetheramine but preferably about 1.6 percent to reduce production time by increasing the rate of gelatinization, and approximately 5 to 40 percent of an alkyl diol such as propylene glycol but preferably about 24.2 percent to produce Product B to react with Product A. Approximately 15 to 60 percent of Product A but preferably about 38.0 is blended with approximately 40 to 85 percent of Product B but preferably about 62.0 percent to produce the desired hydrogel wound dressing of the present invention.

Optionally, 0-5% but preferably 1-3% of an antimicrobial or a bacteriostatic agent can be added to the final reaction mixture or Product B. Suitable such antimicrobial and bacteriostatic agents include bismuth tribromophenate, bacitracin, erythromycin, silver sulfadiazine, idoxuridine, triflurouddine, vidarabine, pyrimethamine. Preferably bismuth tribromophenate or silver sulfadiazine are optionally added to the reaction mixture to decrease the risk of wound infection and odor. The resultant hydrogel wound dressing is characterized in that it comprises 5 to 30 percent by weight of a polyurethane prepolymer but most preferably 23 percent, 3 to 45 percent by weight of polyethylene glycols and propylene glycols but most preferably 30 percent and the balance water, accelerator and optional additives.

The polyurethane hydrogel of the present invention is manufactured as further described in the following examples:

Example A: Hydrogel Produced From Isophorone Diisocyanate based Prepolymer

Ten grams of isophorone diisocyanate prepolymer was mixed thoroughly first with 10.0 grams of polyethylene glycol (Portion A). Then 30.0 grams of deionized water was mixed

with 10.0 grams of propylene glycol and 0.5 grams of polyetherdiamine (Portion B). Portion A and Portion B were mixed thoroughly with a stirring rod for about two to 5 minutes until a homogeneous solution was formed. The solution was then cast into a 4"x4" mold coated with a silicone-polyethylene oxide polymer release agent and maintained undisturbed for 90 minutes at room temperature while the gelatinization reaction occurred. The mold was kept in a closed container at room temperature overnight to prevent water evaporation and to permit essentially complete chemical reaction of all isocyanate end groups. The final hydrogel upon removal from the mold was flexible, transparent and able to absorb 40 to 50 percent its own weight in one hour.

Example B: Hydrogel Produced from Toluene Diisocyanate based Prepolymer

Five grams of polyethylene glycol was mixed with five grams of toluene diisocyanate prepolymer (Portion A). Then fifteen grams of deionized water was mixed with seven grams of propylene glycol and 0.7 grams of polyetherdiamine (Portion B). Portion A and Portion B were quickly mixed and cast into two aluminum weighing dishes coated with silicone-polyethylene oxide copolymer release agent. The material gelatinized within 30 minutes. Both dishes filled with the hydrogel material were kept in a closed container at room temperature overnight to prevent water evaporation and to permit essentially complete chemical reaction of all isocyanate end groups. The final hydrogel material upon removal from the dishes was flexible, transparent and able to absorb 40 to 50 percent its own weight in one hour.

**Example C: Hydrogel Produced with bacteriostatic agent
Bismuth Tribromophenate (BTP)**

A hydrogel with BTP was formed by repeating the preparation of Example A, except 0.6 grams of BTP was added to Portion
5 B. The final hydrogel was flexible and able to absorb 40 to 50 percent its own weight in one hour.

**Example D: Hydrogel Produced with antimicrobial Silver
Sulfadiazine (SSD)**

A hydrogel with SSD was formed by repeating the preparation
10 of Example A, except 0.2 grams of SSD was added to Portion B. The final hydrogel was flexible and able to absorb 40 to 50 percent its own weight in one hour.

Once the subject hydrogel is blended as described in detail in the above Examples, the hydrogel may be cast and
15 molded in any size or shape but is preferably molded into ropes having a length ranging from about two to twelve inches but preferably between four to eight inches and a width ranging from 0.1 to 2 inches but preferably about 0.25 to 1.75 inches or into disks having a diameter ranging
20 between one and twelve inches but most preferably between two and six inches for ease of use. The thickness of the disks and ropes may vary substantially from .01 to 1 inch in thickness but most preferably are molded to .1 inch to .75 inch in thickness for ease of use with acceptable
25 absorption.

The unexpected significant advantages of the present hydrogel dressing achieved through the particular reaction

ratios noted above include increased absorption capabilities and increased strength. The increased strength of the subject hydrogel material eliminates the need for backing material as described in the prior art. Additionally, the hydrogel is stable, does not become brittle or crack with moisture loss, and has an extended shelf-life over other such materials.

The subject hydrogel dressing so produced is clear unless altered by additives such as bacteriostatic or antimicrobial agents and the like. After the hydrogel is cast, molded, and formed, which usually takes approximately one half hour to an hour at room temperature. The gelatinization time can be shortened by curing the hydrogel at a higher temperature. The hydrogel once formed may be exposed to low temperatures such as below 0° C for approximately one half to four hours but preferably approximately one to two hours to extract excess water and to fully complete the reactions described above. This extraction of excess moisture significantly and unexpectedly increases the absorptive capabilities of the subject wound dressing which is capable of absorbing approximately 2 to 6 times its weight.

The subject hydrogel dressing is packaged and sterilized using an appropriate sterilization technique or may be sterilized and then packaged using aseptic technique. Appropriate methods of sterilization and packaging are known to those skilled in the art and include gamma radiation, electronic beam, ethylene oxide and like methods of sterilization. Preferably, the subject hydrogel wound dressing is packaged and then sterilized using gamma radiation by cobalt 60 with 1 to 3 mrad but preferably 2 mrad in two independent exposure cycles.

Appropriate packaging for the subject hydrogel wound dressing includes metallic foil pouches such as aluminum foil pouches, polyethylene film, ethylene vinyl acetate film, polypropylene film, polyvinyl chloride film, and like packages known to those skilled in the art.

The method of using the subject hydrogel wound dressing includes removing the dressing from its packaging and placing the dressing on or in a wound. Depending on the amount of exudate draining from a wound site, the dressing should be changed approximately every 1 to 2 days. The dressing in rope form can also be used for deep tunnel wounds. The dressing may be cut using aseptic technique to a size appropriate for a particular wound before placing the dressing on the wound.

If after cutting the subject wound dressing the unused portion experiences water loss, the same may be rehydrated using aseptic technique and sterilized water.

It is seen therefore that the present hydrogel wound dressing provides an effective moist wound dressing to maintain draining wounds in a clean protected state. The wound dressing and method of making and using the same disclosed herein has specific advantages over the heretofore known means of treating draining wounds. The subject wound dressing eliminates risks associated with the treatment of draining wounds, lessens tissue damage upon removal thereof and may be cut to the appropriate size for ease of placement and use. Hence, for these reasons as well as others, some of which hereinabove set forth, it is seen that the present hydrogel wound dressing represents a significant advancement in the art which has substantial commercial significance.

While there is shown and described herein certain specific embodiments of the invention, it will be manifest to those skilled in the art that various modifications may

be made without departing from the spirit and scope of the
underlying inventive concept and that the same is not
limited to the particular forms herein shown and described
except insofar as indicated by the scope of the appended
5 claims.

Claims:

WHAT IS CLAIMED IS:

1. A hydrogel composition comprising from 5 to 30 percent by weight of a polyurethane prepolymer, from 3 to 45 percent by weight of one or more alcohols selected from the group consisting of polyethylene glycol, polypropylene glycol and propylene glycol, and the balance water and accelerator.
2. The hydrogel composition of claim 1 wherein a bacteriostatic agent is added to reduce wound odor and risk of infection when used as a wound dressing.
3. The hydrogel composition of claim 1 wherein a bacteriostatic agent selected from the group consisting of bismuth tribromophenate, bacitracin and erythromycin is added to reduce wound odor and risk of infection when used
5 as a wound dressing.
4. The hydrogel composition of claim 1 wherein bismuth tribromophenate is added to reduce wound odor and risk of infection when used as a wound dressing.
5. The hydrogel composition of claim 1 wherein an antimicrobial agent is added to reduce wound odor and risk of infection when used as a wound dressing.
6. The hydrogel composition of claim 1 wherein an antimicrobial agent selected from the group consisting of silver sulfadiazine, idoxuridine, trifluorouddine,

vidarabine and pyrimethamine is added to reduce wound odor
5 and risk of infection when used as a wound dressing.

7. The hydrogel composition of claim 1 wherein silver sulfadiazine is added to reduce wound odor and risk of infection when used as a wound dressing.

8. The hydrogel composition of claim 1 wherein said composition is approximately 0.01 to 1.00 inch in thickness.

9. The hydrogel composition of claim 1 wherein said composition is formed in the shape of a disc with a diameter ranging from approximately 1.0 inches to 12.0 inches.

10. The hydrogel composition of claim 1 wherein said composition is formed in the shape of a rope with length ranging from approximately 2 inches to 12 inches and width from 0.10 to 2.00 inches.

11. The hydrogel composition of claim 1 wherein said composition is capable of absorbing approximately 2 to 6 times its weight in fluid.

12. A hydrogel wound dressing comprising from 5 to 30 percent by weight of a polyurethane prepolymer, from 3 to 45 percent by weight of one or more alcohols selected from the group consisting of polyethylene glycol, polypropylene
5 glycol and propylene glycol, and the balance water and accelerator.

13. The hydrogel wound dressing of claim 12 wherein a bacteriostatic agent is added to reduce wound odor and risk of infection.

14. The hydrogel wound dressing of claim 12 wherein a bacteriostatic agent selected from the group consisting of bismuth tribromophenate, bacitracin and erythromycin is added to reduce wound odor and risk of infection.

15. The hydrogel wound dressing of claim 12 wherein bismuth tribromophenate is added to reduce wound odor and risk of infection.

16. The hydrogel wound dressing of claim 12 wherein an antimicrobial agent is added to reduce wound odor and risk of infection.

17. The hydrogel wound dressing of claim 12 wherein an antimicrobial agent selected from the group consisting of silver sulfadiazine, idoxuridine, trifluorouddine, vidarabine and pyrimethamine is added to reduce wound odor
5 and risk of infection.

18. The hydrogel wound dressing of claim 12 wherein silver sulfadiazine is added to reduce wound odor and risk of infection.

19. The hydrogel wound dressing of claim 12 wherein said dressing is approximately 0.01 to 1.00 inch in thickness.

20. The hydrogel wound dressing of claim 12 wherein said dressing is formed in the shape of a disc with a diameter ranging from approximately 1.0 inches to 12.0 inches.

21. The hydrogel wound dressing of claim 12 wherein said dressing is formed in the shape of a rope with length ranging from approximately 2 inches to 12 inches and width from 0.10 to 2.00 inches.

22. The hydrogel wound dressing of claim 12 wherein said dressing is capable of absorbing approximately 2 to 6 times its weight.

23. A method of producing a hydrogel composition comprising:

forming a first solution of polyurethane prepolymer and polyethylene glycol;

5 forming a second solution of water, propylene glycol and accelerator; and

combining said first solution with said second solution.

24. The method of claim 23 wherein 15 to 60 percent of said first solution is combined with 40 to 85 percent of said second solution. ^

25. The method of claim 23 wherein 38.0% of said first solution is combined with 62.0% of said second solution.

26. The method of claim 23 wherein said second solution includes a bacteriostatic agent.

27. The method of claim 23 wherein said second solution includes a bacteriostatic agent selected from the group consisting of bismuth tribromophenate, bacitracin and erythromycin.

28. The method of claim 23 wherein said second solution includes bismuth tribromophenate.

29. The method of claim 23 wherein said second solution includes approximately 5 percent by weight bismuth tribromophenate.

30. The method of claim 23 wherein said second solution includes an antimicrobial agent.

31. The method of claim 23 wherein said second solution includes an antimicrobial agent selected from the group consisting of silver sulfadiazine, idoxuridine, trifluorouddine, vidarabine and pyrimethamine.

32. The method of claim 23 wherein said second solution includes silver sulfadiazine.

33. The method of claim 23 wherein said second solution includes approximately 2 percent by weight silver sulfadiazine.

34. A method of using the hydrogel composition produced in claim 23 comprising sterilizing said hydrogel composition and placing said hydrogel composition on or in a wound.

35. The method of claim 23 wherein said combined first and second solutions are cast, molded and heated.

36. The method of claim 23 wherein said combined first and second solutions are cast and molded to form a wound dressing approximately 0.01 to 1.0 inch thick.

37. The method of claim 23 wherein said combined first and second solutions are cast and molded to form a wound dressing in the shape of a disc with a diameter ranging from approximately 1.0 inch to 12.0 inches.

38. The method of claim 23 wherein said combined first and second solutions are cast and molded in the shape of a rope approximately 2 to 12 inches in length and 0.1 to 2.0 inches in width.

39. The method of claim 23 wherein said combined first and second solutions form a hydrogel in approximately 15 minutes to 120 minutes at room temperature.

40. The method of claim 23 wherein said combined first and second solutions after gelatinization are exposed to a low temperature for approximately one half to four hours.

41. The method of claim 23 wherein said combined first
5 and second solutions after gelatinization are exposed to a low temperature of approximately 0° C for approximately one half to four hours.

42. The method of claim 23 wherein said combined first and second solutions form a hydrogel which may be sterilized.

43. The method of claim 23 wherein said combined first and second solutions form a hydrogel which is sterilized by gamma radiation.

44. A hydrogel composition comprising polyurethane prepolymer, polyethylene glycol, propylene glycol, polyetherdiamine and water.

45. A hydrogel composition comprising approximately 30 weight percent polyurethane prepolymer, approximately 20 weight percent polyethylene glycol, approximately 12 weight percent propylene glycol, approximately 1 weight percent
5 polyetherdiamine and approximately 37 weight percent water.

46. The hydrogel composition of claim 1 wherein said accelerator is selected from the group consisting of sodium carbonate, carbonate salts, sodium hydroxide, sodium citrate, potassium phosphate, ammonia and C₁₋₁₂
5 polyalkoxyamines.

47. The hydrogel composition of claim 1 wherein said accelerator is polyetherdiamine.

48. A hydrogel composition of claim 1 comprising polyurethane prepolymer, polyethylene glycol, propylene glycol, polyetherdiamine and water.

49. A hydrogel composition of claim 1 comprising approximately 30 weight percent polyurethane prepolymer, approximately 20 weight percent polyethylene glycol, approximately 12 weight percent propylene glycol,
5 approximately 1 weight percent polyetherdiamine and approximately 37 weight percent water.

50. The hydrogel composition of claim 1 wherein said accelerator is selected from the group consisting of sodium carbonate, carbonate salts, sodium hydroxide, sodium

citrate, potassium phosphate, ammonia and C₁₋₁₂
5 polyalkoxyamines.

51. The hydrogel composition of claim 1 wherein said accelerator is polyetherdiamine.

52. A method of producing a hydrogel wound dressing comprising:

forming a first solution of polyurethane prepolymer and polyethylene glycol;

5 forming a second solution of water, propylene glycol and accelerator; and

combining said first solution with said second solution.

53. The method of claim 52 wherein 15 to 60 percent of said first solution is combined with 40 to 85 percent of said second solution.

54. The method of claim 52 wherein 38.0% of said first solution is combined with 62.0% of said second solution.

55. The method of claim 52 wherein said second solution includes a bacteriostatic agent.

56. The method of claim 52 wherein said second solution includes a bacteriostatic agent selected from the group consisting of bismuth tribromophenate, bacitracin and erythromycin.

57. The method of claim 52 wherein said second solution includes bismuth tribromophenate.

58. The method of claim 52 wherein said second solution includes approximately 5 percent by weight bismuth tribromophenate.

59. The method of claim 52 wherein said second solution includes an antimicrobial agent.

60. The method of claim 52 wherein said second solution includes an antimicrobial agent selected from the group consisting of silver sulfadiazine, idoxuridine, trifluorouddine, vidarabine and pyrimethamine.

61. The method of claim 52 wherein said second solution includes silver sulfadiazine.

62. The method of claim 52 wherein said second solution includes approximately 2 percent by weight silver sulfadiazine.

63. A method of using the hydrogel composition produced in claim 23 comprising sterilizing said hydrogel composition and placing said hydrogel composition on or in a wound.

64. The method of claim 52 wherein said combined first and second solutions are cast and molded.

65. The method of claim 52 wherein said combined first and second solutions are cast and molded to form a wound dressing approximately 0.01 to 1.0 inch thick.

66. The method of claim 52 wherein said combined first and second solutions are cast and molded to form a wound

dressings in the shape of a disc with a diameter ranging from approximately 1.0 inch to 12.0 inches.

67. The method of claim 52 wherein said combined first and second solutions are cast and molded in the shape of a rope approximately 2 to 12 inches in length and 0.1 to 2.0 inches in width.

68. The method of claim 52 wherein said combined first and second solutions form a hydrogel in approximately 15 minutes to 120 minutes at room temperature.

69. The method of claim 52 wherein said combined first and second solutions after gelatinization are exposed to a low temperature for approximately one half to four hours.

70. The method of claim 52 wherein said combined first and second solutions after gelatinization are exposed to a low temperature of approximately 0° C for approximately one half to four hours.

71. The method of claim 52 wherein said combined first and second solutions form a hydrogel which may be sterilized.

72. The method of claim 52 wherein said combined first and second solutions form a hydrogel which is sterilized by gamma radiation.

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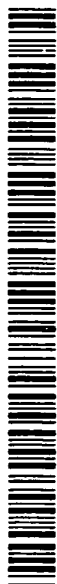


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(54) Title: **HYDROGEL WOUND DRESSING AND THE METHOD OF MAKING AND USING THE SAME**

(57) Abstract: A hydrogel wound dressing which is highly absorptive, contours to a wound side and maintains the wound in a moist state to promote healing thereof.

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61L 15/26, A61L 15/60

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0426422 A2 (NDM ACQUISITION CORP.), 8 May 1991 (08.05.91), claims 1-4,7-9, abstract --	1-72
X	EP 0455324 A1 (NDM ACQUISITION CORP.), 6 November 1991 (06.11.91), claims 1,9,15-16, abstract --	1-72
X	EP 0536875 A1 (NDM ACQUISITION CORP.), 14 April 1993 (14.04.93), claims 1,2,7-9, abstract --	1-72

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INTERNATIONAL SEARCH REPORT

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US 4226232 A (WAYMAN R. SPENCE), 7 October 1980 (07.10.80), claims 7,11-16, abstract -- -----	2-7,13-18, 26-33,55-62

INTERNATIONAL SEARCH REPORT
Information on patent family members

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